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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/044,463

01/10/2002

Davide R. Grassetti

107-000110US

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04/30/2008

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/044,463	<b>Applicant(s)</b> GRASSETTI ET AL.	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-16 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7, 9 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 10-12, 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on February 14, 2008 has been entered.

### *Claim Rejections 35 U.S.C. 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are directed to a method comprising administer the disulfide compounds herein to an individual in need of immune response modulation. Examples of those individuals are given in the specification, paragraphs 0095-0102, e.g., immune compromised patients (0100), patients with Lentivirus infection (paragraph 0099) is one of the examples. The effective amounts are defined as about 10 µg to about 5 g per kg of body weight (0087).

3. Claims 1-2, 5-6, 10-12, and 20-24 rejected under 35 U.S.C. 102(b) as being anticipated by Grasseti (US 4,378,364, IDS), as evidenced by Barber et al. (US 5,662,896) and Tagawa. .

4. Grasseti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas, including those undergo chemotherapy, an effective amount of 6,6'-

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dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day. See, particularly, the examples, and the abstract and the claims. As to “modulating an immune response,” or other limitations that further define the immune response (claims 10-12), recited in the preamble, it is noted that preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

5. The added step in the claimed method: “identifying an individual in need of immune response modulation;” is inherently met by the method of treating cancer patient disclosed in the reference, as cancer patients are recognized as “in need of immune response modulation” See, the abstract in Tagawa and columns 1-2 in Barber et al.

6. Further, applicant’s attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter anticipated by the prior art.

### **Response to the Arguments**

7. Applicants’ amendments and remarks submitted February 14, 2008 have been fully considered. The rejection of claims 23 and 24 over Henderson et al. (USPN 6001555) is

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withdrawn in view of the amendment of claim 23. However, the amendments and remark are not persuasive with respect to the rejections over Grasseti (US 4,378,364, IDS).

8. Applicants argue that not all cancer patients are in need of immunomodulation, particularly, applicants contend that

Barber, at columns 1 and 2 cited by the Office, makes it clear that cancer patients are not necessarily in need of immune modulation. For example, at column 1, line 35, Barber suggests that 30% of patients treated with surgery alone will have no recurrence. These cancer patients were not treated with immune modulators and did not need them. Chemotherapies and radiation therapies also have success without resort to immunomodulation

9. The arguments are untenable. The fact that some of the cancer patients are treated without the employment of immunomodulation does not mean those patients are not immune compromised. All cancer patients are somewhat immune compromised and therefore would meet the limitation of "patient in need thereof" herein. See, paragraph 0100 of the specification herein. Further, Grasseti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas, including those undergo chemotherapy. Those undergo chemotherapy and with pain are deemed to be immune compromised.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/  
Primary Examiner, Art Unit 1617